

evaluated. The Board did not discuss the generic concept that both Capon and Eshhar described -- the concept of selecting and combining a gene sequence encoding the variable domain of an antibody and a sequence encoding a lymphocyte activation protein, into a single DNA sequence which, upon expression, allows for immune responses that do not occur in nature. The record does not show this concept to be in the prior art, and includes experimental verification as well as potential variability in the concept.

Whether the inventors demonstrated sufficient generality to support the scope of some or all of their claims, must be determined claim by claim. The Board did not discuss the evidence with respect to the generality of the invention and the significance of the specific examples, instead simply rejecting all the claims for lack of a complete chimeric DNA sequence. As we have discussed, that reasoning is inapt for this case. The Board's position that the patents at issue were merely an "invitation to [**31] experiment" did not distinguish among the parties' broad and narrow claims, and further concerns enablement more than written description. See *Adang v. Fischhoff*, 286 F.3d 1346, 1355 (Fed. Cir. 2002) (enablement involves assessment of whether one of skill in the art could make and use the invention without undue experimentation); *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993) (same). Although the legal criteria of enablement and written description are related and are

often met by the same disclosure, they serve discrete legal requirements.

The predictability or unpredictability of the science is relevant to deciding how much experimental support is required to adequately describe the scope of an invention. Our predecessor court summarized in *In re Storrs*, 44 C.C.P.A. 981, 245 F.2d 474, 478, 1957 Dec. Comm'r Pat. 361 (CCPA 1957) that "it must be borne in mind that, while it is necessary that an applicant for a patent give to the public a complete and adequate disclosure in return for the patent grant, the certainty required of the disclosure is not greater than that which is reasonable, having due regard to the subject matter involved." This aspect may [**32] warrant exploration on remand.

In summary, the Board erred in ruling that § 112 imposes a *per se* rule requiring recitation in the specification of the nucleotide [**1361] sequence of claimed DNA, when that sequence is already known in the field. However, the Board did not explore the support for each of the claims of both parties, in view of the specific examples and general teachings in the specifications and the known science, with application of precedent guiding review of the scope of claims.

We remand for appropriate further proceedings.

VACATED AND REMANDED

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 09/756,096 Confirmation No.: 5647
Applicant : MITCHELL et al.
Filed : January 8, 2001
TC/A.U. : 1633
Examiner : Janet L. Epps Ford
Docket No. : 027705.00024
Customer No. : 38485
For : METHODS AND COMPOSITION FOR USE IN SPLICEOSOME
MEDIATED RNA *TRANS*-SPLICING

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Date: June 6, 2006

TERMINAL DISCLAIMER PURSUANT TO 37 C.F.R. 37 C.F.R. 1.321(c)

Sir:

Intronn, Inc., the owner of the entire interest in U.S. Application Serial No. 09/756,096 filed on January 8, 2001 entitled "METHODS AND COMPOSITION FOR USE IN SPLICEOSOME MEDIATED RNA *TRANS*-SPLICING", which is a continuation-in-part of application serial number 09/158,863 filed September 23, 1998 (U.S. Patent No. 6,280,978), which is a continuation-in-part of serial number 09/133,717 filed on August 13, 1998 (U.S. Patent No. 6,083,702), which is a continuation-in-part of serial number 09/087,233 filed on May 28, 1998 (abandoned), which is a continuation-in-part of application serial number 08/766,354 filed on December 13, 1996 (U.S. Patent No. 6,013,487), which claims benefit to provisional application number 60/008,717 filed on December 15, 1995, as evidenced by an assignment to

Intronn, Inc., which has been submitted to the U.S. Patent and Trademark Office on February 4, 1999, Reel/Frame No. 9740/0688 (copy attached hereto) along with an Assignment in which Intron Holdings, LLC is assigning its rights to Intronn, Inc., hereby disclaims the terminal part of the statutory term of any patent granted on the above-identified application, which would extend beyond the expiration date of the full statutory term, defined in 35 U.S.C. § 154 to 156 and 173, of commonly owned issued U.S. Patent Nos. 6,013,487 and 6,280,978. The owners hereby agree that any patent so granted on the above-identified application shall be enforceable only for and during such period that the above-identified application and granted U.S. Patent Nos. 6,013,487 and 6,280,978 are commonly owned. This agreement shall run with any patent granted on the instant application and shall be binding upon the assignees, their successors, or assigns.

The undersigned is attorney of record and has the authority to execute this Terminal Disclaimer on behalf of Intronn, Inc., and has reviewed the above-referenced assignments and hereby certifies that, to the best of my knowledge and belief, title is in the assignees on whose behalf this terminal disclaimer is being filed.

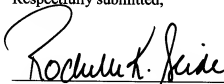
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Payment of the filing fee in the amount of \$65.00, pursuant to 37 C.F.R. §1.20 (d), is to be made according to the Credit Card Payment Form attached herewith. Applicants believe that

Appl. No. 09/756,096
Reply to Office Action of January 6, 2006
Response dated June 6, 2006

no additional fees are required in connection with this filing. However, if additional fees are required, the Commissioner is hereby authorized to charge any additional payment, or credit any overpayment, to Deposit Account No. 01-2300, **referencing Docket Number 027705.00024.**

Respectfully submitted,

A handwritten signature in cursive script, reading "Rochelle K. Seide", is written over a horizontal line.

Rochelle K. Seide, Ph.D.
Registration No. 32,300
ARENT FOX PLLC
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New York, NY 10019
Tel. No. (212) 484-3945
Fax No. (212) 484-3990
Customer No. 38485

ASSIGNMENT

WHEREAS, INTRON HOLDINGS, LLC (hereinafter "ASSIGNOR") having an office and place of business at 14428 Marine Drive, Silver Springs MD, is the owner, by assignment from LLOYD G. MITCHELL to ASSIGNOR, recorded in the United States Patent and Trademark Office Reel 8516, Frame 0234 of an invention entitled "CHIMERIC RNA MOLECULES GENERATED BY TRANS-SPlicing," as set forth and described in Letters Patent, United States Patent No. 6,013,487, issued on January 11, 2000, and in corresponding foreign applications listed in Schedule A attached hereto; and

WHEREAS, INTRON, Inc. (hereinafter "ASSIGNEE"), having its principal place of business at 840 Main Campus Drive, Suite 3500, Raleigh, North Carolina 27606, is desirous of acquiring ASSIGNOR's whole right, title and interest in and to said invention and any and all improvements thereon, and in and to the said Letters Patent and any and all continuations, divisions, continuations-in-part, extensions, substitutions, renewals and reexaminations thereof;

NOW, THEREFORE, TO ALL WHOM IT MAY CONCERN, BE IT KNOWN, that the said ASSIGNOR, for and in consideration of the sum of One (\$1.00) Dollar lawful money of the United States to it in hand paid by said ASSIGNEE, at or before the executing and delivery of these presents, the receipt of which is hereby acknowledged, has sold, assigned, transferred and conveyed, and by these presents does sell, assign, transfer and convey unto said ASSIGNEE, its successors and assigns, ASSIGNOR's entire right, title and interest in and to said invention entitled "CHIMERIC RNA MOLECULES GENERATED BY TRANS-SPlicing," as set forth and described in Letters Patent, United States Patent No. 6,013,487, issued on January 11, 2000, and any and all improvements thereon, and in and to said Letters Patent and any continuations, divisions, continuations-in-part, extensions, substitutions, renewals and reexaminations thereof, and in and to any and all applications for Letters Patent filed in foreign countries for said invention and improvements, including all priority rights under the Paris Convention, and any and all Letters Patent which may be granted in foreign countries therefor, including but not limited to the applications listed on Schedule A attached hereto; TO HAVE AND TO HOLD THE SAME to the full end of the term or terms for which any and all said Letters Patent may be granted;

AND the said ASSIGNOR, for the considerations aforesaid, does hereby covenant and agree to and with the said ASSIGNEE, its successors and assigns, that it has the full power to make this assignment and that the rights assigned are not encumbered by any grant, license or right heretofore given, and that said ASSIGNOR, its successors and assigns, shall and will do all lawful acts and things, and procure or make, execute, and deliver any and all other instruments in writing and any and all further application papers, affidavits, assignments or other documents which in the opinion of counsel for said ASSIGNEE, its successors or assigns, may be required or necessary in this or in any foreign country more effectively to secure to and vest in said ASSIGNEE, its successors and assigns, the whole right, title and interest in and to said improvements and invention, Letters Patent, applications for Letters Patent, rights, title, benefits, privileges and advantages hereby sold, assigned, transferred and conveyed or intended so to be,

including, but not limited to, the right to bring a cause of action for infringement on any claim arising prior to the effective date of this assignment.

Subscribed and executed at 380 Edmund Mill Rd., Raleigh, NC 27602
(Place)

on September 27, 2001
(Date)

By Lloyd G. Mitchell
Name: Lloyd Mitchell
Title: President and CEO of Intron Holdings, LLC

NOTARIAL CERTIFICATE

BE IT KNOWN, that on this 27 day of September, 2001, before me personally came Lloyd Mitchell, to me known to be the person mentioned in and who executed the foregoing assignment, and acknowledged to me that he executed the same as his free act and deed for the use and purposes therein mentioned.



Amanda K. Johnson
Notary Public

My commission expires 5-13-2004



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

MAY 05, 1999

PTAS

BAKER & BOTTS, L.L.P.
CARMELLA L. STEPHENS
30 ROCKEFELLER PLAZA - 44TH FL
NEW YORK NY 10112



100959606A

UNITED STATES PATENT AND TRADEMARK OFFICE
NOTICE OF RECORDATION OF ASSIGNMENT DOCUMENT

THE ENCLOSED DOCUMENT HAS BEEN RECORDED BY THE ASSIGNMENT DIVISION OF THE U.S. PATENT AND TRADEMARK OFFICE. A COMPLETE MICROFILM COPY IS AVAILABLE AT THE ASSIGNMENT SEARCH ROOM ON THE REEL AND FRAME NUMBER REFERENCED BELOW.

PLEASE REVIEW ALL INFORMATION CONTAINED ON THIS NOTICE. THE INFORMATION CONTAINED ON THIS RECORDATION NOTICE REFLECTS THE DATA PRESENT IN THE PATENT AND TRADEMARK ASSIGNMENT SYSTEM. IF YOU SHOULD FIND ANY ERRORS OR HAVE QUESTIONS CONCERNING THIS NOTICE, YOU MAY CONTACT THE EMPLOYEE WHOSE NAME APPEARS ON THIS NOTICE AT 703-308-9723. PLEASE SEND REQUEST FOR CORRECTION TO: U.S. PATENT AND TRADEMARK OFFICE, ASSIGNMENT DIVISION, BOX ASSIGNMENTS, CG-4, 1213 JEFFERSON DAVIS HWY, SUITE 320, WASHINGTON, D.C. 20231.

RECORDATION DATE: 02/04/1999

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NUMBER OF PAGES: 3

BRIEF: ASSIGNMENT OF ASSIGNOR'S INTEREST (SEE DOCUMENT FOR DETAILS) ^{RECEIVED}
BAKER & BOTTS, L.L.P.

ASSIGNOR:

MITCHELL, LLOYD G.

DOC DATE: 01/07/1999 99 MAY 13 AM 11:58

ASSIGNOR:

GARCIA-BLANCO, MARIANO A.

DOC DATE: 12/23/1998

TO

ASSIGNEE:

INTRON HOLDINGS, LLC
14428 MARINE DRIVE
SILVER SPRING, MARYLAND 20905

SERIAL NUMBER: 09158863
PATENT NUMBER:

FILING DATE: 09/23/1998
ISSUE DATE:

STEVEN POST, EXAMINER
ASSIGNMENT DIVISION
OFFICE OF PUBLIC RECORDS

COPY TO

RUSCUS 5/14/99

ASSIGNMENT

WHEREAS, WE, LLOYD G. MITCHELL, a citizen of the United States, residing in the City of Durham, State of North Carolina, whose post office address is 4500 Highgate Drive, Durham, NC 27713, and MARIANO A. GARCIA-BLANCO, a citizen of the United States, residing in the City of Durham, state of North Carolina, whose post office address is 12 Sanderling Court, Durham, North Carolina 27713 have made an invention entitled "METHODS AND COMPOSITIONS FOR USE IN SPLICEOSOME MEDIATED RNA TRANS-SPLICING" as set forth and described in application for Letters Patent of the United States Serial No. 09/158,863, filed September 23, 1998; and

WHEREAS, INTRONN HOLDINGS, LLC, having an office for the transaction of business at 14428 Marine Drive, Silver Spring, MD, 20905 is desirous of acquiring the entire right, title and interest in and to said invention and any improvements thereon, and in and to the said application for Letters Patent therefor, and any Letters Patent which may be obtained therefor;

NOW, THEREFORE, TO ALL WHOM IT MAY CONCERN, BE IT KNOWN, that WE, the said LLOYD G. MITCHELL and MARIANO A. GARCIA-BLANCO, for and in consideration of the sum of One Dollar (\$1.00), lawful money of the United States, to us in hand paid by said INTRONN HOLDINGS, LLC, and other valuable considerations unto us moving from said INTRONN HOLDINGS, LLC, at or before the ensembling and delivery of these presents, the receipt of which is hereby acknowledged, have sold, assigned, transferred and conveyed and by these presents do sell, assign, transfer and convey, unto said INTRONN HOLDINGS, LLC, its successors and assigns, the entire right, title and interest in and to the said invention entitled "METHODS AND COMPOSITIONS FOR USE IN SPLICEOSOME MEDIATED RNA TRANS-SPLICING" as set forth and described in application for Letters Patent of the United States Serial No. 09/158,863, filed September 23, 1998, and any and all improvements thereon, and in and to said application and any division, continuation or continuation-in-part thereof, and in and to any Letters Patent of the United States which may be issued on any of said applications, and any reissues thereof, and in and to any and all applications for Letters Patent filed in foreign countries for said invention or improvements, including all priority rights under the Paris Convention, and any and all Letters Patent which may be granted in foreign countries therefor, TO HAVE AND TO HOLD THE SAME to the full end of the term or terms for which any and all said Letters Patent may be granted;

AND WE, the said LLOYD G. MITCHELL and MARIANO A. GARCIA-BLANCO, do hereby authorize and request the Commissioner of Patents and Trademarks to issue the said Letters Patent of the United States to said INTRONN HOLDINGS, LLC, as the assignee of the entire right, title and interest in and to the same,

for the sole use and behoof of said INTRONN HOLDINGS, LLC, its successors and assigns;

AND, WE, the said LLOYD G. MITCHELL and MARIANO A. GARCIA-BLANCO, for the considerations aforesaid, do hereby covenant and agree to and with said INTRONN HOLDINGS, LLC, its successors and assigns, that we have the full power to make this assignment, and that the rights assigned are not encumbered by any grant, license or right heretofore given, and that we, our executors or administrators, shall and will do all lawful acts and things and make, execute and deliver without further compensation, any and all other instruments in writing, further applications, papers, affidavits, powers of attorney, assignments, and other documents which, in the opinion of counsel for said INTRONN HOLDINGS, LLC, its successors and assigns, may be required or necessary to more effectively secure to and vest in said INTRONN HOLDINGS, LLC, its successors and assigns, the entire right, title and interest in and to said invention and improvements, applications, Letters Patent, rights, benefits, privileges and advantages hereby sold, assigned, transferred and conveyed, and that we will sign any applications for reissue which may be desired by the owner of the patent or patents which may be issued for the said invention or improvements.

IN WITNESS WHEREOF, I, the said LLOYD G. MITCHELL, have hereunto set my hand and seal on the date below written.

Lloyd G. Mitchell
LLOYD G. MITCHELL

STATE OF NC)
: ss.:
COUNTY OF Suham

BE IT KNOWN, that on this 14 day of January, ¹⁹⁹⁹~~1998~~, before me personally came LLOYD G. MITCHELL, to me known and known to me to be the person mentioned in and who executed the foregoing assignment, and he acknowledged to me that he executed the same as his free act and deed for the use and purposes therein mentioned.

Dale D. Yates
Notary Public

my comm exp 5/20/2003